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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,257	01/30/2006	Herbert Schwarz	HABERMANN-1	5164

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EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
02/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,257	SCHWARZ ET AL.	
	Examiner	Art Unit	
	LEI YAO	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,6 and 9-26* is/are pending in the application.

4a) Of the above claim(s) *5-6, 13-21, are 24-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-12,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/29/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Amendment and Arguments

The Amendment filed on 11/3/2008 in response to the previous Non-Final Office Action (6/27/2008) is acknowledged and has been entered.

Claims 1-4 and 7-8 are cancelled.

Claims 5-6 and 9-26 are pending.

Claims 5-6, 13-21, are 24-26 were withdrawn for non-elected invention.

Claims 9-12 and 22-23, drawn to a method of treating CD137 expressing tumor to the extent of B cell lymphoma and fibrosarcoma (elected) and antagonist antibody BBK-2 (elected), are under consideration.

Information Disclosure Statement

The information disclosure statement (s) (IDS) submitted on 9/29/2009 are/is considered by the examiner and initialed copies/copy of the PTO-1449 are/is enclosed.

Rejections Withdrawn

The rejection of claims 1-4, 7, and 8 under *Claim Rejections - 35 USC § 101 and 112 2nd Paragraph* because the claims reciting "use of a CD137 antagonist is withdrawn in view of the cancellation of the claims.

The rejections of claims 1-4, 7, and 8 under 35 U.S.C. 102(b) as being anticipated by B. Kwon (US Patent No. 6303121, issued Oct 2001) is withdrawn in view of the cancellation of the claims.

The rejections of claims 9-10, and 22 under 35 U.S.C. 102(b)s as being anticipated by Aruffo et al., or Kim are withdrawn in view of applicant's evidence and argument on that the antibodies used by Aruffo and Kim are agonist, not antagonist antibodies.

The rejection of claims 9, 11, and 12 under 35 U.S.C. 103(a) as being unpatentable Aruffo et al., are withdrawn in view of applicant's evidence and argument on that the antibodies used by Aruffo and Kim are agonist, not antagonist antibodies.

Rejection Maintained and Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 7-12, 22 and 23 remain and are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwon B. (US Patent 6303121 issued Oct. 2001) in view of Broll et al., (Am J Clin Pathol, Col 115 page, 543-549, 2001) or Schwarz et al (Blood, vol 85, page 1043-1052, 1995).

Claims are amended to be drawn to a method of treating tumor comprising lymphoma with antagonist antibody to CD137comprising administering to a patient in need thereof an effect amount of CD137 antagonist (elect antibody).

Specification teaches antagonist antibody to CD137, BBK-2 (page 8).

Applicant argues that Kwon disclose agonistic antibody BBK-1 and BBK-4 and antagonist antibody BBK-2 and BBK-3. Kwon uses only agonist antibody to treat tumor.

The argument has been considered but is not found to be persuasive for the following reasons:

First, the amended claims recite active step of administering to a patient in need thereof an effect amount of CD137 antagonist antibody. The claims require any patient who needs a CD137 antibody, do not limit the patient having tumor. Kwon teaches "the antagonist antibody BBK-2 and BBK-3 are used to upregulate the immune system or suppress its activity and some of tumors are immunogenic" (col 5, line 30+). Kwon also teaches "by interfering with ligand binding, as with the use of an anti-H4-1BB (CD137) mAb antagonist BBK-2 and BBK-3, the immune responses will be suppressed. In this context, diseases that would benefit from the therapeutic use of such a mAb include rheumatoid arthritis, systemic lupus erythematosus, and diabetes" (col 5, line 50+). Based on the teachings of Kwon, a patient in need thereof includes a patient with tumor, arthritis, or diabetes etc. Thus, Kwon teaches antagonist antibody, a patient, and active step of administering the antibody.

Second, antagonist antibody BBK-2 and BBK-3 are known antibodies disclosed by Kwon and used in the instant application (page 8, line 12+). It would have the same effect on the patients with the same disease.

It is known that CD137 is TNF receptor family member expressed on activated T-cell lymphocyte and tumor cells. Interaction between CD137 and its ligand or agonist will enhances the lymphocyte activation against tumor growth. CD137 expression leads to TGF secretion by tumor cells, which inhibits anti-tumor immune response. In this application, Applicant proposes a different mechanism that decreases function or expression of CD137 protein on tumor cells to reduce the tumor mass. However, the claims, as written, recite an active method step of administering the same antagonist antibody BBK-2 to a patient in need thereof. The claims do not limit the patient having a specific disease, tumor, HIV or autoimmune disease. Thus, claimed invention is unpatentable over the references in combination because the claimed method uses the same materials, operates with the same method step, and treats the same patient (a patient in need thereof). Applicant is recommended to amend the claims drawn to treating a patient with tumor or lymphoma in the active method step. However, such amended claims may be subjected to a new ground rejection, such as under USC 112, 1st paragraph if application does not provide enough evidence to show claimed invention enabled or Applicant having possession at time of filing the application.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lei Yao/
Examiner, Art Unit 1642

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643